PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P-2670/WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/50680	International filing date *(day/month/year)* 02.10.2003	Priority date *(day/month/year)* 14.10.2002
International Patent Classification (IPC) or both national classification and IPC A61L31/16		
Applicant EUROPEAN COMMUNITY, represented by THE ...		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19.03.2004	01.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Pilling, S Telephone No. +49 89 2399-8461

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/50680

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-10 as originally filed

Claims, Numbers

1-11 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 11

   because:

   ☒ the said international application, or the said claims Nos. 11 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-10
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-10
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claim 11 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no international preliminary examination will be made in respect of this claim (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. The following documents; D1 to D5 are referred to in this communication; this designation results from the order of citation found in the International Search Report and will be adhered to in the rest of the procedure. **Reference to the passage(s) cited in respect of each citation in the search report will be made unless otherwise specified.**

3. None of the documents cited in the present search report disclose an intravascular stent comprising an enzyme capable of catabolizing cholesterol/lipids and/or cells that produce such an enzyme. Hence, the subject matter of Claims 1 to 10 is new and meets the requirements of Article 33(2) PCT.

4. The subject matter of Claims 1 to 10 is considered to be inventive for the following reasons;

   the present claims are directed towards intravascular stents comprising a cholesterol/lipid catabolizing enzyme or cells producing such an enzyme. On the basis of the present disclosure (see the first paragraph of the description) it appears that the use of such enzymes prevents obstructive artherosclerotic lesions and restenosis. The closest prior art appears to be any of documents D1 to D3. These documents each disclose that stents may be coated with cholesterol reducing agents. Although no particular agents are mentioned it would appear that such agents would provide broadly the same technical effects as the present invention, *i.e* prevention of obstructive artherosclerotic lesions and restenosis. Thus the objective problem to be

solved in respect of the present invention appears to be "How to prevent obstructive artherosclerotic lesions and restenosis". The Applicant has solved this problem by selecting enzymes (or cells producing these enzymes) as the cholesterol/lipid reducing agents. There is no teaching or suggestion in any of the prior art documents (D1 to D5) towards the use of cholesterol/lipid catabolizing enzymes for preventing artherosclerotic lesions and restenosis. This authority does not consider that cholesterol / lipid catabolizing agents would have inevitably been considered by one of skill in this art who would naturally have turned first to the more convention anticholesterol agents such as statins. Moreover, the teaching of documents D1 to D3 involving drug delivery to the body appears quite different to that of the present application wherein enzymes are immobilised on a stent and achieve their technical effects *in situ*. Thus, it does not appear that the teaching of any of documents D1 to D3 would have inevitably led to the presently claimed invention.

Hence the subject matter of Claims 1 to 10 is inventive and meets the requirements of Article 33(3) PCT.